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ABSTRACT

The recent requirement for education on the protection of human research subjects mandated by the federal government has the potential to impact research in all fields, including education, significantly. At this point, all key personnel involved in research using human subjects are either required or strongly recommended (depending on the type of institution) to be trained, tested, and certificated, verifying that they have completed education relating to the protection of research subjects from harm. A history of the requirement, clarification of when and to whom it applies, and possible implications are discussed. Because of this additional hurdle, there is the risk that research protocols will be modified to reduce the use of human subjects or be abandoned altogether. However, potential benefits of the requirement are also outlined. (Contains 20 references.) (Author/SLD)

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# Requirements for Education on the Protection of Human Research Subjects: Implications for Educational Researchers

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**Abstract.** The recent requirement for education on the protection of human subjects mandated by the federal government has the potential to significantly impact research in all fields, including education. At this point, all key personnel involved in research utilizing human subjects are either required or strongly recommended (depending on their type of institution) to be trained, tested, and certificated, verifying that they have completed education relating to the protection of research participants from harm. A history of the requirement, clarification of when and to whom it applies, and possible implications are discussed. Due to this additional hurdle there is the risk that research protocols will be modified to reduce the use of human subjects, or be abandoned altogether. However, potential benefits of the requirement are also outlined.

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# Requirements for Education on the Protection of Human Research Subjects: Implications for Educational Researchers

On September 17, 1999 Jesse Gelsinger died following complications of a gene therapy experiment conducted at the University of Pennsylvania. Since that day, Mr. Paul Gelsinger, Jesse's father has worked diligently within private and legislative arenas to try to understand how the death of his son could have been prevented. His inquiries led to Congressional testimonies and court appearances seeking justice for not only his son, but for many other research participants who had been harmed while participating in research.

Unfortunately the Gelsinger case is not isolated. History has laid the foundation for where we as researchers find ourselves today. The biomedical sciences have been guilty of a number of atrocities, many widely publicized, though usually after the fact, however, the non-medical arena is not untarnished. Research in the behavioral and social sciences includes such examples as Stanley Milgram's (1994b) obedience experiments. In attempting to demonstrate that individuals will all supposedly obey given the right conditioning, Milgram (1994a) summed up his position by saying, "It is ironic that the virtues of loyalty, discipline and self sacrifice that we value so highly in the individual are the very properties that create destructive organization engines of war and bind men to malevolent systems of authority" (pp. 261-262). While supposedly well intentioned, Milgram's studies are now used as examples of unethical research because of the potential harm they caused his subjects; not physically but mentally.

It is a faint gray line at best, that is drawn between the behavioral and biomedical fields of research.

> Some biomedical research pertains to behavior (e.g., in psychiatry, neurology, or epidemiology), and many of the methods used in behavioral research, such as observation and the questioning of subjects, are also used in biomedical research. Research may be designed to evaluate the behavioral changes that result from a biomedical intervention (e.g., lessening of depression after taking a particular medication or changes in psychiatric disorders following hemodialysis) or to examine physiological responses to behavioral interventions (e.g., lowering of blood pressure through biofeedback or weight loss through hypnosis) (OHRP, 2001).

How short-sighted are the statements -- *We are not cutting anyone. There is no risk in simply asking questions.* What are commonly accepted as the *soft risks* can be just as harmful as physical injury. A breach of confidential information, embarrassment due to a connection between a research subject and his or her responses, loss of social standing, or loss of relationships can be psychologically harmful. The fact that subjects can be harmed but not physically injured, or physically injured but not necessarily harmed is true for both biomedical and non-medical fields.

## History of the Requirement

The need for protection of human research subjects has been apparent in recent years with well publicized shutdowns of all research at institutions such as The University of Alabama at Birmingham (UAB) in January, 2000 (Hansen & Spencer, 2000), Duke University in April, 2000, and Johns Hopkins in July, 2001 (Curry, 2001) for a period of time due to human subjects protection issues. Individual researchers have also been suspended due to human subjects

research violations (Robeznieks, 2001a) as well, some of them quite noteworthy. These cases underscore the oversight and importance being placed on human subjects currently. The progression of federal laws, regulations, and policies relating to education on the protection of human research subjects are shown in Table 1.

Table 1

History of Federal Requirements for Education on the Protection of Human Research Subjects

| Date | Policy | Requirement | Penalty for Noncompliance |
|---|---|---|---|
| 6/13/2000 | 65 Fed. Reg. 37137 | Office for Human Research Protections (OHRP) created with three divisions: Policy and Assurance, Compliance Oversight and *Education and Development* | |
| 10/1/2000 | NIH Education Requirement Notice OD-00-039 dated June 5, 2000 | All key personnel submitting grant applications to NIH | Funding not awarded |
| 8/15/2000 | Office of Research Compliance and Assurance [ORCA] IL #01-15 Online Educational Materials: Update | Veterans Health Affairs (VHA) researchers (PIs, Co-PIs, and Co-Investigators) wishing to conduct VHA-funded research must provide documentation of education and/or training obtained over the previous three years on human subjects protection | Research will not be approved and may not be initiated |
| 12/2000 | Initiated Federalwide Assurance (FWA) | "research investigators complete appropriate institutional educational training *before* [italics added] conducting human subject research" | Not tested |
| 9/5/2001 | NIH Education Requirement Clarification Notice OD-01-061 | Extended education requirement to key personnel at consortium institutions or performance sites | Funding not awarded |

NIH Education Requirement

In October 1999, the Secretary for the Department of Health and Human Services, Donna Shalala, accepted a recommendation made by the Commission on Research Integrity to extend the education requirement for the responsible conduct in research (RCR) to include those conducting federally-supported Public Health Service (PHS) research ("DHHS/NIH announce new initiatives", 2000). Additionally, as a part of the increased vigilance with regard to the treatment of human subjects, the National Institutes of Health (NIH) imposed new regulations for education of individuals involved in human subjects research.

The NIH policy reads:

> Beginning on October 1, 2000, the NIH implemented a policy requiring education on the protection of human research participants for all key personnel submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for projects involving human research participants (NIH: Office of Extramural Research, 2000, June 5).

The June 5, 2000 Notice OD-00-039 goes on to define key personnel as "all individuals responsible for the design and conduct of the study." The background for this measure was described as part of a new initiative to "strengthen government oversight of medical research." A later NIH notice (NOT-OD-01-061) clarified that the "education requirement also applies to key personnel at consortium institutions or performance sites if they are participating in research that involves human subjects" (NIH: Office of Extramural Research, 2001, September 5).

Further clarification of the NIH policy stated "All new and non-competing grant applications submitted [to NIH] beginning October 1, 2000, must *describe* [italics added] the education all 'key personnel' have received in the protection of human subjects" (Federal Grants News for Colleges and University, July/August 2000, p. 1). At a meeting of the Council on Governmental Relations (COGR), Dr. Wendy Baldwin, Deputy Director of Extramural Research at NIH, discussed the various announcements noting additionally that the policy notice required investigators to *describe* [italics added] the completed education before funds would be awarded. Adding to the mounting list of changes, DHHS announced the transfer of the Office for Protection from Research Risks (OPRR) from NIH to a new, *elevated* office, the Office for Human Research Protections (OHRP). Its three divisions, Policy and Assurance, Compliance Oversight and *Education and Development*, would report directly to the Assistant Secretary for Health (65 Fed. Reg. 37137, June 13, 2000).

45 CFR 46

Many researchers may feel comfortable that, because they are not receiving NIH funding or conducting any otherwise federally funded research, they are exempt from the education requirement. However, institutions which receive any type of Department of Health and Human Services (DHHS) support are governed by the DHHS Regulations for the Protection of Human Subjects, commonly known as Title 45 Code of Federal Regulations Part 46 (45 CFR 46), and all research conducted at these institutions is classified as federally-supported by federal regulations. Subpart A of 45 CFR 46 is known as the "Common Rule," and has been adopted by all branches of the federal government involved in human subjects research. It is within these regulations that Institutional Review Boards (IRBs) are mandated for each institution.

Federalwide Assurance (FWA)

Most sizable institutions come under what is known as an assurance. Formerly most had (some still do) a Multiple Project Assurance (MPA) which ensured that all research conducted at that institution would comply with OHRP guidelines. MPAs were written specifically for each institution. In December 2000, OHRP developed what is known as a Federalwide Assurance (FWA), which provides that not only the institution, but, like the MPA, that each individual researcher will do no harm and conduct research following ethical standards. The difference between the FWA and the MPA, is that the FWA is uniform across all institutions. The FWA identifies an institutional official and establishes a partnership between the federal government and the institution to guarantee that all research, not just funded research, will be assessed prior to initiation to verify that human research participants will be protected. While MPAs are still honored, they are converted to FWAs as they expire (usually a term of three years). Educational training is covered in the FWA, which will now be the standard for all institutions with assurances. The wording in the FWA terms is

> OHRP *strongly recommends* [italics added] that the Institution and the designated IRB(s) establish educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IRB members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with, relevant ethical principles, relevant Federal Regulations, OHRP guidance, other applicable guidance, state and local laws, and institutional policies for the protection of human subjects. Furthermore, OHRP recommends that a) IRB members and staff complete relevant educational training *before* [italics added] reviewing human subject research; and b) research investigators complete appropriate institutional educational training *before* [italics added] conducting human subject research (Federalwide Assurance of Protection for Human Subjects, 2002).

For the sake of consistency, institutions conducting federally-supported research and covered under FWAs (or MPAs) review all research the same, regardless of the source of funding or whether, in fact, the project is funded or not. It is for this reason that policies are applied in *blanket-fashion* to all researchers at an institution. The benefits are that this consistency serves to simplify the research protection process by eliminating necessity for determining which research falls under which guidelines and also promotes public trust.

Veteran's Administration Interpretation of the Requirement

While *strongly recommends* is not a mandate, it has been interpreted as such by the Veteran's Administration. In an August 15, 2000 memorandum, the Office of Research and Development (ORD) established a new requirement related to investigator education on human subjects protection for Veterans Health Affairs (VHA) researchers (PIs, Co-PIs, and Co-Investigators) wishing to conduct VHA-funded research. ORD gave January 1, 2001, as a deadline for completion and documentation of education and/or training obtained over the previous three years (Office of Research Compliance and Assurance [ORCA] IL #01-15 Online Educational Materials: Update). Within the same day, John R. Feussner, Chief Research and Development Officer for the Department of Veterans Affairs, issued the same statement and added, "This documentation must be on file at the local office *prior to* [italics added] submission and review of any new proposals…" (J. R. Feussner, personal communication, August 15, 2000, p. 1).

Affiliation with VA research facilities has elevated the education requirement from a strong recommendation to a requirement for many institutions. Our institution and others that are affiliated with the VA are bound by Fuessner's edict for training prior to submitting research proposals. While non VA-affiliated institutions may choose to disregard the *strong recommendation,* in most cases regarding the safeguarding of human subjects we have promoted erring on the side of caution. It would seem that meeting that requirement would be on the side of caution.

## Modes of Institutional Compliance

Let us assume for the sake of argument that institutions are bound by the requirement for educating key personnel in human subjects protection, as we consider ourselves to be at our institution. How are institutions meeting the educational requirement for so many researchers? Initially there were education modules online, provided by NIH, which anyone could utilize and be *certificated* as having been trained. These were provided because of the short timeline to have researchers trained (June 5, 2000, the announcement was issued that researchers would have to be trained, and all were to have met that requirement by October 1, 2000). However, it was up to each institution to begin developing their own program for educating investigators and key personnel in the protection of human subjects and be able to verify this for Federal auditors. A variety of methods have been designed including in-house online modules, workshops, and seminars lasting several hours or several days in order to train everyone from students to experienced researchers. Education is necessary, but not sufficient to meet Federal requirements. Researchers and other key personnel must also be evaluated somehow in order to verify that they understand critical factors involved in the protection of human subjects. Our institution, which includes a regional university campus, medical college campus, and VA medical facility, provides a three-hour training, two brief online modules, and a written test on which the minimum passing score is 85%.

Research dollars flow in the billions, supporting both non-medical and medical research, yet without human subjects, dollars would be worthless. Therefore it is to the advantage of researchers and institutions to protect subjects both out of ethical obligation as well as to maintain public trust in the research community so that in the future individuals will be willing to participate in research. Education in human subject protection is important not only for the new researcher, but for the experienced investigator as well. An adult serious about receiving a quality education concerned for their future vocation would not enroll in a college or university that did not offer an accredited program. By the same token, it is unlikely that a potential research participant would be willing to engage in research being conducted by researchers who were either employed by an institution or who themselves had failed to *earn* and *maintain* the public trust. Long gone are the days when the directives of an individual whose name is followed by M.D., Ph.D., Ed.D., Sc.D. or any other D., were followed without question. With the failures of human subject research presented alongside media advertisements seeking research enrollees, potential subjects are more informed and perhaps more skeptical than in the past.

## Informing Researchers

Part of the dilemma faced by institutions which are responsible for the oversight of research performed under their watch is that people conducting research may be unaware that

what they are doing would be classified as research. At some institutions there are still many researchers who don't realize they are required to seek IRB approval or exemption of their research, much less that there are education requirements (or at least *strong recommendations* for education) for the research personnel. The degree to which the new education requirements are emphasized and publicized obviously varies from institution to institution. However, there is probably no institution at which every researcher or potential researcher is fully aware of the new requirements. The necessary education really begins at the point of defining research, which according to 45 CFR 46 is defined as:

> (d) *Research* [italics in original] means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities (Protection of Human Subjects, §46.102).

In other words, some researchers need to be educated in order to know that they need to be educated.

Grant funded projects generally pass through so many hands prior to study activation, that there are many opportunities for researchers to be made aware of the need for education and many points within the process for verification of education to take place. Non-funded projects are more likely to slip by without education requirements being met. Some institutions have begun requiring verification of education prior to approval of research projects by the IRB, as previously mentioned in the VA policy. This is effective for enforcing the education requirement for those researchers who understand that research protocols must pass through the IRB and comply, but does not address those who are unaware that their project must be reviewed by an IRB in the first place.

## Implications for Research

Assuming that researchers are aware of the new push for education and for whom, there are several possible implications for research and researchers, some positive and some negative.

### Research May Be Carried Out More Ethically

The primary impetus for the education requirement was to ensure that human subjects who participate in research would be treated ethically. Hopefully this is and will continue to be the case and will only be improved by having better educated human subjects researchers.

### Public Trust May Be Enhanced

A second potential positive outcome of increasingly well-trained researchers is that as research participants have contact with key personnel working within research projects, they may be better informed of their rights as research participants. Also, not only should participants be less likely to be harmed in the research process, but also may see it as a more positive experience than if the research personnel had not been trained. This would contribute to the public trust of research mentioned previously.

Less Research May Be Performed

However, there are several more negative possibilities created by new education policies. There is the possibility that potential researchers will choose not to undertake research they might have otherwise carried out because of the inconvenience of participating in training or ensuring that key personnel have completed training. The same could be said for traversing the IRB approval process as well. There are probably potential research projects that have never been initiated because of the inconvenience of obtaining IRB approval, but the new education requirements add one more hurdle, although a noble one, to the pre-research process. The primary implications of this possibility are that knowledge that would have been gained from that research is not and researchers forfeit the gratification and personal and professional growth that comes from conducting the research.

Research Designs May Be Modified

A second negative possibility is that research designs will be modified to reduce or eliminate the use of human subjects. Similarly, in the past, with restrictions on conducting research with children being made more stringent, there has been concern that children might be excluded from virtually all research (Robenznieks, 2001). While this removes risks of participating in a particular research study, it also reduces the knowledge gained about children, which would be beneficial. Again, eliminating the use of human subjects would reduce the amount of information gained from a study, either making it less informative, or even useless, whereas a study employing human subjects might be vastly more useful.

Third, because the education requirements extend to all key personnel at all research sites, researchers may tend to limit the number of key personnel and/or sites involved in a study. This could have two implications. One would be that smaller scale studies may be performed, which tend to have less external validity, and the second would be that fewer individuals have the opportunity to be involved in the conduct of research. While modifying research to avoid the use of human subjects, limiting study sites, limiting study personnel, and the abandonment of research projects altogether are not unethical, they do have negative implications. All may result in the reduction of new knowledge that would have been gained from research.

Researchers May Fail to Seek IRB Approval

A fourth possibility, and one that borders on unethical, is that some researchers will not seek IRB approval for their studies because of the added burden of having to document training for themselves and all key personnel. This could actually result in more potential risk for research participants than existed prior to the mandate for education. Of course, if this were to be discovered, the institution could be found "out of compliance" and be forced to suspend research until human subjects research violations were rectified.

Researchers May Falsify Training Documentation

A clearly unethical possibility is that researchers may lie about their training in order to receive study approval. Because institutions are providing their own education, testing, and certificating, the likelihood of this would vary among institutions. Individuals transferring between institutions and those conducting projects that utilize multiple sites would have more of an opportunity for such fabrication.

Requirements May Be Over-interpreted or Misinterpreted

A final possibility is that the requirement for education may be over-interpreted, and thereby too broadly applied, resulting in many of the problems outlined above, or misinterpreted. Education is clearly supported by federal policies at this point (see e.g., 65 Fed. Reg. 37137, June 13, 2000; "DHHS/NIH announce new initiatives", 2000; NIH: Office of Extramural Research, 2000, June 5). However, policies are so new, that few have been tested. It is therefore unclear exactly what penalties will be for failure to comply. The OHRP website currently indicates that comments are being received about the FWA and the *current* version [March, 2002] is available (Federalwide Assurance…, 2002). This implies that changes should be expected, but to ignore this emphasis on education would likely be a choice to have to do planning and implementation of an education plan quickly at a later date.

## Reasons for Compliance

It is assumed that anyone conducting research will comply with the new education requirements, although reasons for compliance will vary. Ideally, researchers will see the benefit to the research subjects and the field of human research in general, and will comply willingly. However, many, if not most, will comply because of the threat of consequences for themselves or their institution. Hopefully, research will only be improved and not curtailed.

## Implications for Educational Researchers

A question of particular interest to educational researchers is whether there are implications that are specific to educational research? Educational researchers within higher education settings typically have access to an IRB and training opportunities and will be held accountable for meeting federal mandates, just as any other researchers within higher education because of the risk to the institution for noncompliance. However, educational researchers who conduct studies at other sites (e.g., K-12 schools) often have no IRB and have less access to training materials and current regulations and may be more likely to violate requirements for the protection of human subjects. Additionally, the determination of whether a project should be classified as research, and therefore governed as research, is difficult within educational settings. What might be classified as research by 45 CFR 46 might appear to a classroom teacher to be a part of regular classroom practice. For example, if a teacher were to teach two Algebra I classes using two different textbooks, compare the knowledge of the two classes at the end of the school year, and present the findings at a national mathematics teaching conference, research has been done. New knowledge was generated and communicated.

At this point, because the recommendation for human subjects education is so new, colleges, universities, and medical schools have been the focus of energy with regard to developing and overseeing compliance. However, as most of those institutions have their programs in order, the focus may broaden to include other organizations. At that point, individuals within schools and school systems will most likely be expected to meet and verify that they have met the human subjects protection education guidelines.

## Implications for Professional Organizations

Finally, what are the implications for professional organizations that sponsor conferences or publish journals in which research findings are shared? Is there any responsibility to verify whether the research was done in compliance with the institution's IRB? While many scholarly journals do ask for authors to sign a statement indicating that research was conducted ethically, most professional presentations do not require such certification. Journals and professional organizations have not historically sought to verify this, nor would it be feasible to do so. Should an organization or journal be concerned about whether an author or presenter has fulfilled the education recommendation, or would that fall under any statement of ethical practice that is already requested? We believe the latter is more practical.

Verification of ethical practices or education probably falls beyond what is likely, or even possible for most journals or organizations, however, professional organizations could provide some of the required education in the ethical treatment of human research subjects as a service to participants. This could serve to make it more likely that researchers were aware of ethical research practices, not only through the content, but also just the publicity of having the topic on the program at a conference.

## Conclusions

While many researchers probably see this new educational recommendation (or requirement, depending on the type of institution) as a burden that will impede their research, it looks as though it is here to stay. It is not clear yet was the results will be for failure to comply. Various types of noncompliance with Federal guidelines regarding human subjects research have resulted in suspension of one investigator's personal research, to the suspension of an entire institution's research. For decades most researchers have followed non-legislatively enacted codes such as the Nuremburg Code, The Declaration of Helsinki, and The Belmont Report for ethical guidance. However, due to the continuation of and publicizing of unethical research practices, the public and certain lawmakers have acted on the belief that oversight needs to be *ratcheted up a notch*. Thus, *strongly recommended* education; and is education not what educational researchers are in the business of promoting?

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